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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/960,020

09/21/2001

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COD-133

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01/10/2008

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EXAMINER

PICKETT, JOHN G

ART UNIT

PAPER NUMBER

3728

MAIL DATE

DELIVERY MODE

01/10/2008

PAPER

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte CHRISTOPHER MCDOWELL

Appeal 2007-4388
Application 09/960,020
Technology Center 3700

Decided: January 10, 2008

Before ERIC GRIMES, RICHARD M. LEBOVITZ, and FRANCISCO C.
PRATS, *Administrative Patent Judges*.

LEBOVITZ, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal from the final rejection of claims 1, 3, 6, 8, 9, 11, 12, and 16. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

STATEMENT OF THE CASE

The claims are directed to a tray for holding surgical fasteners. Surgical fasteners are known in the art “for attaching sutures, bone plates, and connective tissue” (Specification 1: 17-18).

Claims 1, 3, 6, 8, 9, 11, 12, and 16, which are all the pending claims (App. Br. 2), stand rejected under 35 U.S.C. § 103(a) as obvious over Nicholson (U.S. Pat. No. 5,968,044, Oct. 19, 1999) in view of Nguyen (U.S. Pat. No. 5,873,462, Feb. 23, 1999) and Asa (U.S. Pat. No. 6,098,802, Aug. 8, 2000) (Answer 3).

We select claim 1 as representative of the appealed subject matter. *See* 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 reads as follows:

A tray for holding a plurality of surgical fasteners, the tray comprising
a base having a plurality of wells therein, at least two of the surgical fasteners being disposed within respective ones of the plurality of wells; and
a film over the base and the plurality of wells, a weakness in the film over the plurality of wells whereby to more easily allow an instrument to penetrate the film and enter one of the wells;
wherein each of the wells and the surgical fasteners within each well are maintained in a sterile environment regardless if any of the other wells have been opened.

ISSUE ON APPEAL

Claim 1 is directed to a tray for holding surgical fasteners comprising a base and a plurality of wells. Each well has a “film over” it and a “weakness” in the film to allow an instrument “to more easily . . . penetrate the film.” At least two of the surgical fasteners are “disposed within

respective ones of the plurality of wells.” Each well is “maintained in a sterile environment regardless if any of the other wells have been opened.”

The Examiner finds that the prior art teaches containers having a plurality of wells for the sterile storage of medical devices (injection needles and pipettes), where each well has a film covering that permits a well to be separately entered while maintaining the sterility of the other wells (Answer 3-4). The Examiner finds that the prior art describes surgical fasteners in a sterile tray, but not in plurality of wells (Answer 3) as required by claim 1. The Examiner contends that it would have been obvious to persons of ordinary skill in the art to have stored the surgical fasteners in a container (a “tray”) having a plurality of wells (Answer 4).

Appellant contends there would have been no motivation to have stored surgical fasteners in a container having a plurality of wells (App. Br. 4).

We frame this issue in this appeal as follows: whether persons of ordinary skill in the art would have had reason to have stored surgical fasteners in a prior art container having a plurality of wells like those used for holding injection needles or pipette tips.

DISCUSSION

Scope and contents of the prior art

When making an obviousness determination, the scope and contents of the prior art must first be ascertained. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). Thus, we turn to the prior art cited by the Examiner. The following numbered findings of fact (“FF”) summarize the prior art relied upon the Examiner in setting forth the basis of the rejection.

The Nicholson patent

1. Nicholson describes a bone fastener including an expandable member (10) having an axial channel and an elongated or insertion element (34) which is inserted into the channel (Nicholson, at col. 1, ll. 54-56; at col. 4, ll. 60-65; at col. 5, ll. 15-17; col. 8, ll. 16-20; Figs. 1 and 4; Answer 3).

2. A bone fastener is a single-use (i.e., used once) device utilized to attach soft tissue to bone (Nicholson, at col. 12, l. 25 to col. 13, l. 15).

3. Nicholson also describes a surgical fastener kit that includes the expandable member and the insertion element (Nicholson, at col. 3, ll. 25-30; Answer 6).

4. “Preferably, the kit is encased in a sterile tray or other receptacle” (Nicholson, at col. 3, ll. 37-38; Answer 3).

The Nguyen patent

5. Nguyen describes a pen needle dispenser for storing and dispensing sterile injection needles (Nguyen, at col. 1, ll. 5-8; col. 2, ll. 30-34; Answer 4).

6. Each pen needle assembly (100) comprises a plurality of cavities or wells, each of which contains a sterile injection needle (Nguyen, at col. 3, ll. 37-67; Fig. 2; Answer 4).

7. Each cavity (31) is sealed “using a label or sterility barrier 150 that is attached to an upper surface 32 of container 30, which provides sterility for the unused pen needle assemblies in each cavity 31” (Nguyen, at col. 3, ll. 45-50; Fig. 2).

8. The label or sterility barrier can also be scored to allow for controlled breaking of the scored area (Nguyen, at col. 3, ll. 57-67; Answer 4).

9. The needle dispenser provides a convenient way to safely and sterilely store needles which can be individually accessed prior to use, e.g., by persons who must periodically inject doses of medication (Nguyen, at col. 2, ll. 8-13 and 60-65).

10. The needle dispenser also provides a way of disposing of and preventing needles from being reused (Nguyen, at col. 2, ll. 54-59).

The Asa patent

11. Asa describes a rack for pipette tips which comprises a plurality of wells, each well containing one pipette tip, and having a cover to prevent cross-contamination between the wells (Asa, at col. 2, ll. 13-26; Answer 4). The pipette rack can be covered by a combination of pierceable films that ensure the sterility of the individual pipette tips when they are dispensed (Asa, at col. 6, ll. 55-64).

12. "Pipette tips are often disposable" (Asa, at col. 1, l. 17).

Differences between the prior art and the claimed invention

Once the scope and contents of the prior art have been determined, the differences between the prior art and the claimed invention must be identified. *Graham*, 383 U.S. at 17. The following facts are relevant to this determination:

13. Each of Nguyen and Asa describe containers which comprise a plurality of wells or cavities for the sterile storage of disposable medical devices (FF 5-8, 10-12; Answer 3-4).

14. In Nguyen's container for injection needles, each needle is individually stored in a cavity and sealed with a label or sterility barrier that "provides sterility for the unused pen needle assemblies in each cavity 31" (FF 6-7; Nguyen, at col. 3, ll. 37-67; Fig. 2; Answer 4).

15. Nguyen's label or sterility barrier (FF 7, 14) meets the limitations of claim 1 of "a film over the base and plurality of wells", where the film maintains "a sterile environment regardless if any of the other wells have been opened" (Answer 4).

16. The label or barrier can be scored to allow for controlled breakage and access to the sterile needle (FF 8; Nguyen, at col. 3, ll. 57-67; Answer 4) – and thus is "a weakness in the film . . . to more easily allow an instrument to penetrate the film" as recited in claim 1.

17. Nicholson describes a surgical kit comprising a bone fastener encased in a sterile tray or receptacle (FF 2-3; Nicholson, at col. 3, ll. 25-30 and 37-38), but does not describe the tray structure, and in particular, does not describe a tray with a plurality of wells (Answer 3, 6) as required by claim 1.

18. Thus, the difference between the prior art and the claimed invention is that the prior art does not teach surgical fasteners in container having a plurality of wells (FF 17) (Answer 4).

Reason to combine the prior art

Having established the differences between the prior art and the claimed invention, the next step is to identify a reason why persons of ordinary skill in the art would have been prompted to combine the prior art to have made the claimed invention. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

In this case, the Examiner contends that it “would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the disposable surgical fastener assemblies of Nicholson . . . in a tray as taught by either Asa . . . or Nguyen . . . in order to provide independent dispensing of the fasteners” (Answer 4).

We agree with the Examiner’s reasoning and conclusion. The following findings of fact are relevant to this determination:

19. Nicholson teaches that its bone fasteners are preferably stored in a sterile tray (FF 4; Nicholson, at col. 3, ll. 37-38; Answer 3).

20. Nicholson does not describe the structure of the tray (FF 17; Answer 3).

21. However, Nguyen teaches that a multi-cavity container facilitates the sterile storage of injection needles, each held in separate sterile cavity that can be individually accessed through a film barrier without compromising the sterility of the other cavities (FF 5-9).

22. Asa’s multi-well pipette rack shares similar characteristics and advantages for sterile storage with Nguyen’s container (FF 11; Asa, at col. 2, ll. 13-23; Answer 4).

23. Thus, for medical devices which require sterility – such as the bone fasteners of Nicholson (FF 4; Nicholson, at col. 3, ll. 37-38; Answer 3) – the prior art reasonably suggests to persons of skill in the art storing the devices in a plurality of wells, so that one device can be used without comprising the sterility of the other devices (*see* FF 21-22).

Appellant argues that “there is no need to provide a plurality of wells as all of these devices are going to be used during the surgical operation” (App. Br. 5). We are not persuaded by this argument that the Examiner erred.

24. The prior art teaches that disposable single-use medical devices – injection needles in Nguyen (*see* FF 10; Nguyen, at col. 2, ll. 54-59) and pipette tips in Asa (*see* FF 11; Asa, at col. 1, l. 17 and col. 6, ll. 55-64; Answer 4) – are typically stored sterilely in individual wells to permit one device to be used without contaminating devices in neighboring wells.

25. Like injection needles and pipettes, bone fasteners are single-use medical devices (*see* FF 2; Nicholson, at col. 12, l. 25 to col. 13, l. 15; Answer 3).

26. The prior art teaches that it is conventional to package single-use medical devices in multi-well containers, where each well has a sterility barrier to keep its contents sterile (*see* FF 24).

In sum, it is not patentable to use a prior art structure for its known and expected benefits. When “a patent ‘simply arranges old elements with each performing the same function it had been known to perform’ and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR*, 127 S. Ct. at 1740. A suggestion, teaching, or motivation

to combine the relevant prior art teachings does not have to be found explicitly in the prior art. *In re Kahn*, 441 F. 3d 977, 987 (Fed. Cir. 2006). *See also KSR*, 127 S. Ct. at 1741 (The obviousness analysis “can take account of the inferences and creative steps that a person of ordinary skill in the art would employ.”).

Appellant also argues that “there is no mention whatsoever of the cartridge holding the bone fasteners” (App. Br. 5). We do not agree. As pointed out by the Examiner (Answer 6), Nicholson describes the cartridge comprising an expandable member and an insertion element (Nicholson, at col. 16, ll. 14-29). The bone fastener is described by Nicholson as comprising an expandable member and an insertion element (34) (FF 1; Nicholson, at col. 1, ll. 54-56; at col. 4, ll. 60-65; at col. 5, ll. 15-17; col. 8, ll. 16-20; Figs. 1 and 4; Answer 3).

For the foregoing reasons, we affirm the rejection of claim 1. Claims 3, 6, 8, 9, 11, 12, and 16 fall with claim 1 because separate reasons for their patentability were not provided. *See* 37 C.F.R. § 41.37(c)(1)(vii).

TIME PERIOD

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

Ssc:

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Application 09/960,020

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